bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 661378**

Issued To: **United Orthopedic Corporation**
No. 57, Park Ave. 2
Science Park
Hsinchu City
30075
Taiwan

In respect of:

Design and manufacture of total hip and total knee joint implants and their related accessories, and trial sets for total knee arthroplasty, bipolar hip systems and end-user sterilized surgical instruments for connection to an active device.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-02-02** Date: **2020-11-25** Expiry Date: **2024-05-26**

Digitally signed by Chicu Natalia
Date: 2022.05.26 14:25:13 EEST
Reason: MoldSign Signature
Location: Moldova

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 661378**
Date:	**2020-11-25**
Issued To:	**United Orthopedic Corporation** **No. 57, Park Ave. 2** **Science Park** **Hsinchu City** **30075** **Taiwan**

Subcontractor:	**Service(s) supplied**
CeramTec GmbH Medical Products Division Ceramtec Platz 1-9 73207 Plochingen Germany	**Manufacture**
China Biotech Corporation No. 10, 33rd Road Taichung Industrial Park Taichung Taiwan	**Gamma Irradiation**
Lincotek Trento S.p.A. Via Al Dos de la Roda, 60 Z.I. Cire 38057 Pergine Valsugana (TN) Italy	**Surface Treatment**
mdi Europe GmbH Langenhagener Straße 71 30855 Langenhagen Germany	**EU Representative**

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Subcontractor:	**Service(s) supplied**
Orchid Orthopedics Solutions Memphis Location 4600E. Shelby Drive Suite 1 Memphis Tennesee 38118 USA	**Surface Treatment**
Taiwan Advanced Sterilization Technology, Inc. (AST-TW) Taichung Export Processing Zone No. 17-1 Chien Kuo Road Tan Tze Taichung City 42760 Taiwan	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
United Orthopedic Corporation No. 16, Luke 1st Rd. Luzhu Dist. Kaohsiung City 82151 Taiwan	**Manufacture** **Packaging** **Surface Treatment**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 661378**

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Date	Reference Number	Action
02 February 2017	8603489	First issue, transfer from another Notified Body.
27 February 2019	8713229	Scope was updated to cover total hip and total knee implants. The scope "Design and manufacture of sterile cervical and lumber cage systems, bipolar hip implants, partial hip replacement implants, cancellous bone screws, tibial wedges, tibial and femoral augments, offset stem adaptors, trial sets for total knee arthroplasty, and end-user sterilized cervical plate systems, screws fixation systems, vertebral body replacement systems and spinal staple systems" was replaced by "Design and manufacture of sterile cervical and lumber cage systems, total hip and total knee joint implants and their related accessories, and trial sets for total knee arthroplasty, femoral endoprostheses, and sterile and end-user sterilized spinal reconstruction devices". The critical subcontractors United Orthopedic Corporation (Kaohsiung Branch), Eurocoating S.p.A., Orchid Orthopedics Solutions, CeramTec AG, and Taiwan Advanced Sterilization Technology Inc. were added to the list of subcontractors. The crucial suppliers Invibio Inc., Perryman company, and Supra alloys Inc were removed from the list of subcontractors.
08 March 2019	8603491	Traceable to NB 0086.

EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
16 October 2019	8715062	Scope was updated to cover end-user sterilized surgical instruments. mdi Europe GmbH was added to the list of critical subcontractors as EU Representative.
Current	3250892	Certificate Renewal. Certificate scope updated to remove "femoral endoprostheses" and "sterile and end-user sterilized spinal reconstruction devices". Addition of "bipolar hip systems" and "for connection to an active device" to the scope. Subcontractors Eurocoating S.p.A. and CeramTec AG have changed their names to Lincotek Trento S.p.A. and CeramTec GmbH Medical Products Division, respectively.